DSM Anti-Infectives

DSM

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
USA

Your reference	Our reference	Direct line	Delft
	JS/SA/122	+31 152792369	1999, 11 November

Docket No. 99D-0529

Dear Sirs,

Please find hereunder an additional comment from:

DSM Anti-Infectives (Gist-Brocades B.V.)
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on FDA's Draft Guidance "Guidance for Industry: Changes to an Approved NDA or ANDA" (June 1999).

DSM Anti-Infectives, a Business Group of the Dutch company DSM, is one of the world's leading manufacturers of antibiotic APIs and -intermediates. Our Business Group has sixteen wholly- and partly owned manufacturing sites worldwide, and is the holder of more than twenty five DMFs (many of which were formerly approved AADAs for bulk) submitted to and in majority previously reviewed and found acceptable by the FDA.

Our comment relates to page 1, line 13:

The scope of this guidance ("drugs, other than specified biotechnology and specified synthetic biological products") does not match with the scope of the underlying guidance BACPAC 1 ("synthetic drug substances and synthetic steps involved in the preparation of semisynthetic drug substances'). We suggest to adapt the scope of the "changes to an Approved NDA or ANDA" guidance to the BACPAC 1 scope.

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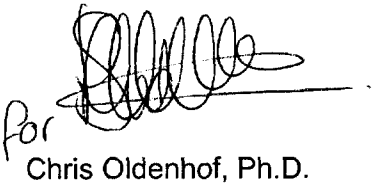
As has been appropriately taken into account by the BACPAC 1 draft, the products excluded from its scope (like fermentation products) should be treated in a way that better suits these categories of products eg. by application of specific guidelines or specific agreements between CDER reviewers and industry.

We hope and trust that both this new Guidance and its companion BACPAC Guidance will, in their final form, provide for procedures and requirements that will enable industry to implement necessary, beneficial and often unavoidable changes in bulk pharmaceutical manufacture.

Sincerely yours,



Chris Oldenhof, Ph.D.
Manager International Regulatory Affairs
DSM Anti-Infectives
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The Netherlands


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